510(k) SUMMARY

Summary of Safety and Effectiveness

Submitter's Name & Address:

Inovise Medical, Inc.

1025 Industrial Parkway, Suite C

Newberg, Oregon 97132

Contact Person & Telephone: Alan Andresen

503/554-4235

Date Summary Prepared:

April 26, 2000

Device Name:

Cardiovise ECG Interpretive Software

510(k) #:

K001349

Predicate Device: Hewlett Packard M1700A Cardiograph (ref. 510(k) #K85520)

Device Description, Intended Use & Effectiveness:

Cardiovise software is an ECG interpretive program designed to be run on a personal computer and is not subject to sterilization. Cardiovise software is a Class II medical device that provides an interpretation of ECG waveforms that is considered by a physician in determining a patient's cardiac conditions.

Cardiovise software is designed to be of assistance to licensed physicians who are performing electrocardiographic analysis of their adult patients. It is intended to be used for patients who may need any of the following: ECG analysis for the evaluation of cardiovascular status, ECG assessment of cardiac health, information concerning specific areas of previous infarction, and/or information concerning left ventricular hypertrophy. Cardiovise software may be used by the physician with patients for whom automated measurements and interpretation of specific points of the electrocardiographic waveform could be of value in diagnosis of cardiac conditions.

Cardiovise software is indicated for use in adult patients undergoing an examination by a health care practitioner in whom an electrocardiographic analysis is desirable.

Technological Characteristics:

Cardiovise software is an interpretive program designed to allow physicians to harness the power of the Cardiovise software algorithms to enhance their ability to diagnose old myocardial infarctions (OMIs) and left ventricular hypertrophy (LVH). The display of the infarction information in both text statements and a pictorial format provides clarity for the physician and improves communication with patients.

Safety:

The Cardiovise software and hardware system presents a non-significant risk to the patient and/or operator for the following reasons:

- The software does not control life-supporting or life-sustaining devices.
- The software does not control the delivery of potentially harmful energy.
- The software does not control the treatment delivery.
- The software does not provide vital sign monitoring nor does it provide alarms for potentially life-threatening situations in which intervention is necessary.
- The software is designed to operate on industry-standard PC hardware components. Risk to the operator due to electrical shock, mechanical injury and thermal shock is mitigated by the use of components that have been pre-qualified by other agencies.
- The software does not provide diagnostic information on which treatment or therapy is based, such that if misapplied could result in serious injury or death.
- The Cardiovise software program serves as a display and processing program aid in the interpretation of the patient's ECG. It is not meant to replace or eliminate the standard overread of the ECG by a licensed medical physician. The physician should integrate all of the patient's clinical and diagnostic information, i.e. the patient's history, prior to making his final interpretation.
- The Cardiovise software program has no direct adverse effect on health since the results represent only a part of the information that a physician will use for his final interpretation. The physician has final responsibility for interpretation of the ECG.

There are no directly applicable standards that apply to this product. Applicable elements of existing standards that relate to the submitted device have been utilized as follows:

Applicable Section

EN 1041	4.1.4	INFORMATION SUPPLIED BY THE
	4.1.8	MANUFACTURER WITH MEDICAL
	4.1.9	DEVICES
EN 980	4.4	TERMINOLOGY, SYMBOLS AND
		INFORMATION PROVIDED WITH
		MEDICAL DEVICES; GRAPHICAL
		SYMBOLS FOR USE IN THE LABELING OF
		MEDICAL DEVICES

EN 60601-1	19	MEDICAL ELECTRICAL EQUIPMENT -
		PART 1. GENERAL REQUIREMENTS FOR
		SAFETY
ANSI/AAMI	*see	DIAGNOSTIC ELECTROCARDIOGRAPHIC
EC11-1991	Note	DEVICES
•	below	
ANSI/AAMI		SAFE CURRENT LIMITS FOR
ES1-1985		ELECTROMEDICAL APPARATUS

*Note: The applicable section is 3.2.15, which in turn refers to ANSI/AAMI ES1-1985.

In addition to the above-referenced standards, AAMI HE48 HUMAN FACTORS ENGINEERING AND PREFERRED PRACTICES FOR THE DESIGN OF MEDICAL DEVICES was used as a general reference in the design of the Cardiovise software user interface and User's Guide.

Summary of Effectiveness:

Testing with annotated databases has demonstrated that the device is safe, effective, and performs within its design parameters as compared with the legally-marketed predicate device.



JUL 27 2000

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Debra A. Olson Official Correspondent Inovise Medical, Inc. 1025 SW Industrial Parkway, Suite C Newberg, OR 97132

Re: K001349

Cardiovise™ ECG Interpretative Software

Regulatory Class: II (two)

Product Code: 74 MWJ Dated: April 27, 2000 Received: April 28, 2000

Dear Ms. Olson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III

Director

Division of Cardiovascular and Respiratory Devices Office of Device Evaluation Center for Device

and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: Cardiovise ECG Interpretative Software, Model #

Applicant: Inovise Medical, Inc.

510(k) Number: K001349

Cardiovise is indicated for use in adult patients undergo care practitioner in whom an electrocardiographic analysis	oing an examination by a health ysis is desirable.
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(PLEASE DO NOT WRITE BELOW THIS LINE-CO IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (
	·
Presciption UseOR	Over-The-Counter Use
Division of Cardiovascular & Respiratory Devices 510(k) Number	